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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,525	11/12/2003	Marwan Abboud	21819-119CONCON	8291
31292	7590	04/24/2006	EXAMINER	
CHRISTOPHER & WEISBERG, P.A. 200 EAST LAS OLAS BOULEVARD SUITE 2040 FORT LAUDERDALE, FL 33301			PEFFLEY, MICHAEL F	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/706,525	ABBOUD ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-20 is/are allowed.
- 6) ☒ Claim(s) 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's amendments and comments, received March 9, 2006, have been fully considered by the examiner. In particular, it is noted that applicant has renumbered the claims 13-23 as suggested by the examiner. The following is a complete response to the March 9, 2006 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claim 1 is objected to because of the following informalities: as amended, line 5 recites "wherein the distal end of the first handle" and should apparently recite "wherein the distal end of the first handle". Appropriate correction is required.

Claim Rejections - 35 USC § 102

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Neilson et al (5,733,319).

Neilson et al disclose a catheter system comprising a handle portion (30 – Figure 2A) having first and second flow paths (94B, 96B). A pressure sensor (130) is provided that communicates the pressure of fluid in the fluid pathway (see Abstract). The pressure sensor is used to control the fluid delivered to the system (Abstract). As discussed at column 12 of the Neilson et al patent, a control system allows for the control of the delivery of the fluid based on the monitored temperature and/or pressure of the fluid in the circulation system. The control system is also inherently operable to terminate delivery of the fluid (i.e. if an errant temperature/pressure is detected). The

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pressure at the distal end of the return lumens is inherently less than the pressure at the supply lumen inlet.

Claims 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Imran et al (5,348,554).

Imran et al disclose a flexible catheter (col. 2, line 42) having first (52) and second (53) flow paths for circulating a coolant from a coolant source (61). Pressure sensors (P1 and P2) may be used to determine the pressure of the circulated fluid and are operative to terminate fluid flow. The fluid source is pressurized via pump (66) and the second path is in communication with a vacuum source (71) that applies negative pressure to the second lumen. The pressure sensor is also operative to detect a leak in the system (i.e. by showing a discrepancy in the sensor readings).

Response to Arguments

Applicant's arguments with respect to claim 21 and the Neilson et al reference, filed March 9, 2006, have been fully considered but they are not persuasive.

Applicant contends on pages 4 and 5 of the response that Neilson discloses using the sensor feedback for "adjustment of the temperature and flow rate" to cool tissue, but that Neilson never discloses or suggests "terminating fluid flow". First, it is the examiner's position that the language "the pressure sensor is operative to terminate fluid flow" is merely a statement of the intended use of the sensor. That is, a sensor, per se, can not terminate fluid flow. The sensor would need to be connected to a control mechanism such that the control signal would allow for the termination of the

fluid flow. Claim 21 fails to recite any specific control mechanism to perform the termination of fluid flow, and the statement that the pressure sensor is "operative to terminate fluid flow" is deemed to be broadly interpreted as "capable of sending a signal that may terminate fluid flow". Clearly, the Neilson et al pressure sensor is capable of sending such a signal. Moreover, the examiner maintains that feedback systems such as taught by Neilson et al that control a flow rate would intuitively include means to terminate fluid flow should the feedback signal be proportionally large enough to indicate that such a condition would necessitate a shut down. That is, abnormally large pressure values would indicate the system is overloaded or unsafe and fluid flow should be terminated. The examiner maintains that termination of sources in a feedback system are generally well known. However, the examiner also maintains that applicant's claims fail to recite the necessary structure and/or means for performing the function and that the function is merely a recitation of intended use.

Regarding the Imran et al reference, the examiner again maintains that the pressure sensors are "operative to terminate fluid flow" since the user may see a dangerous pressure level and turn off the fluid source. The Imran et al reference is newly cited to meet the limitations now added to independent claim 22.

Allowable Subject Matter

Claims 13-20 are allowed. Applicant's amendment to claim 13 has overcome the prior art of record and rewritten the claim in a manner substantially analogous to applicant's U.S. Patent No. 6,440,126. The Terminal Disclaimers filed with the March 9, 2006 response are acceptable and have obviated the double patenting issues.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

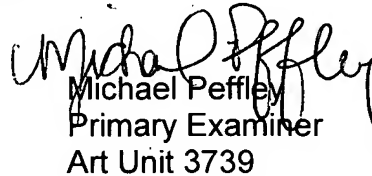
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
April 19, 2006